DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

JUN - 1 1998

Albert P. Mayo
Director, Regulatory Affairs
Organon
375 Mount Pleasant Avenue
West Orange, NJ 07052

RE: **NDA# 20-713**
Mircette (desogestrel/ethinyl estradiol and ethinyl estradiol) Tablets
MACMIS ID# 6580

Dear Mr. Mayo:

Through routine monitoring and surveillance, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of a press release for Mircette that is false, misleading, and otherwise in violation of the Federal Food, Drug and Cosmetic Act. The press release (West Orange, NJ, April 22, 1998) is entitled "Organon Receives FDA Approval to Market Mircette."

Specifically, DDMAC has the following objections:

1. The press release claims that Mircette has "advanced technology," and that its "uniqueness is based on the patented shortened hormone-free interval." These claims imply that Mircette is superior to other oral contraceptives because of its formulation and its period of hormone-free days. These claims are considered to be false or misleading because they are not substantiated by adequate and well-controlled comparative trials. Further, there is no known clinically significant effect of the period of hormone-free days.

2. The press release implies that Mircette's formulation is beneficial because adding estrogen during the hormone-free interval will help women "experiencing menstrual migraines and other inter-menstrual side effects such as dysmenorrhea and pre-menstrual syndrome." Mircette is not indicated for these conditions, and these claims are considered to be false or misleading without substantiation by adequate and well-controlled trials.

3. The press release is lacking in fair balance because there is no risk information presented.

DDMAC requests that Organon immediately discontinue the use of the above press release and any other promotional materials, or activities, that involve similar violative messages. Organon should respond, in writing, with its intent to comply with DDMAC's request by June 12, 1998. This response should include a description of Organon's plan for addressing the issue.

If you have any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds you that only written communications are considered official.

In all future correspondence regarding this matter, please refer to the MACMIS ID # 6580 in addition to the NDA number.

Sincerely,

Lisa L. Stockbridge, Ph.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications